Amendment Dated: December 7, 2004 Reply to Office Action of December 1, 2004

## **REMARKS/ARGUMENTS**

This is in response to the Office Action mailed December 1, 2004 for the above-captioned application. Reconsideration and further examination are respectfully requested.

### **Drawings**

The Examiner objects to the drawings under 37 C.F.R. 1.83(a). The Examiner states that: the drawings must show every feature specified in the claims. Therefore, the wrapper must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Applicant chooses to address this rejection by providing an additional drawing sheet which contains new Figure 9. Figure 9 illustrates the helical suture instrument and apparatus contained within wrapper 90. No new matter has been added as the wrapper was disclosed both in paragraph 0023 of the Specification and by Claim 8.

#### Claim Rejections - 35 U.S.C. §112

The Examiner rejects Claim 5 under 35 U.S.C. §112 on the view that it is "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Specifically, the examiner states that "there is insufficient antecedent basis" for the limitations of "the extensions" in line 1 of Claim 5.

Applicant presents the following Amended Claim 5.

5. The apparatus of claim 1, further characterized in that a width is defined by the extension in a first direction and a second direction of the spatulate member, the width

Page 13 of 21

Amendment Dated: December 7, 2004
Reply to Office Action of December 1, 2004

being less than one-third of the length along a first axis of the spatulate member.

The Applicant respectfully requests reconsideration of Claim 5.

# Claim Rejections - 35 U.S.C. §102

#### Claim 1

The Examiner rejects Claim 1 under 35 U.S.C. 102(b) on the view that it is anticipated by Irwin 2634674.

#### The Examiner states that Irwin

Teaches an apparatus having a first end and a second end, the first end comprising a spatulate member having a length along a first axis; the second end comprising a guide shaped to receive a cylindrical axle for rotation of a second axis, the guide shaped to constrain the first axis in a fixed position relative to the second axis, the first and second axes constrained to lie within a single plane; the spatulate member extending in a first direction and a second direction being on opposite sides of the plane...

# Claim 1 as currently amended is quoted below.

1. (currently amended) An apparatus having a first end and a second end, the first end comprising a spatulate member having a length along a first axis; the second end comprising a guide shaped to receive a cylindrical axle for rotation on a second axis, the guide shaped to constrain the first axis in fixed position relative to the second axis and extending for a second length, the first and second axes constrained to lie within a single plane; the spatulate member extending in a first direction and a second direction from the first axis, the first direction and second direction being on opposite sides of the plane, the spatulate member extending along its first axis away from the guide for a distance greater

Amendment Dated: December 7, 2004 Reply to Office Action of December 1, 2004

than the second length.

Applicant respectfully requests that the rejection to Claim 1 be withdrawn. The above Amendment to Claim 1 was made at the Examiner's invitation and was faxed to the Examiner at (571) 273-4698 on November 22, 2004. The Examiner had communicated to the Applicant's Attorney that it was important to receive various changes to the claims as soon as possible. Applicant thanks the Examiner for requesting the new claims. The office of Applicant's Attorney contacted the Examiner on November 23, 2004 and the Examiner stated that he had received the faxes but had not yet had a chance to review them. The office of Applicant's Attorney contacted the Examiner again on November 24, 2004 and again the Examiner stated that he had not yet had a chance to review the faxes. The office of Applicant's Attorney left a message regarding the Amendments on November 30, 2004. It appears however, that the Examiner did not take these amendments into account in rendering this office action, as the above rejection appears to be based on the content of the text of Claim 1 prior to the November 22 amendment. Out of abundance of caution, all of the Claims that were amended in the fax of November 22, 2004 are provided again in the listing of claims included with this office action response.

Unlike the "spatulate member" of currently amended Claim 1, the spatulate member of Irwin (as defined by the Examiner's handwritten notations on the Figure included within the text of the office action) does not extend along its first axis away from the guide for a distance greater than the second length.

Again, Applicant respectfully requests that the Examiner withdraw this rejection to Claim 1. Review of Claim 1 as currently amended is requested.

Page 15 of 21

Amendment Dated: December 7, 2004
Reply to Office Action of December 1, 2004

### Claims 4, 6, and 10

The Examiner rejects Claims 4, 6, and 10 under 35 U.S.C. 102(b) on the view that they are anticipated by Irwin 2634674.

The Examiner states that the guide of Irwin "comprises two member[s] each extending toward the second axis from the first axis, each of the two member[s] having a hole shaped to receive the cylindrical axle; wherein the spatulate member is symmetric relative to the first axis, further characterized as made of metal."

Claims 4, 6, and 10 are dependent on independent Claim 1. As stated above, Claim 1 was amended prior to the mailing of this office action and the new amendment has not yet been considered by the Examiner. Applicant respectfully requests that the Examiner withdraw this rejection to Claims 4, 6, and 10. Review of Claims 4, 6, and 10 with respect to currently amended Claim 1 is requested.

### Claim Rejections - 35 U.S.C §103

The Examiner rejects Claims 7-9 under 35 U.S.C. §103 on the view that they are unpatentable over Irwin.

#### Claim 7

For convenience, Claim 7 is quoted below.

7. The apparatus of claim 1 further characterized as being sterile.

The Examiner states that:

Irwin teaches an apparatus made of metal. It should be noted that Irwin fails to specifically teach where the apparatus is sterile. However, the metal is fully

Page 16 of 21

Amendment Dated: December 7, 2004
Reply to Office Action of December 1, 2004

capable of being made sterile.

The undersigned does not agree with the Examiner's view that Claim 7 is unpatentable. Just because an apparatus is "capable of being sterile" does not mean that it would be obvious to make that apparatus sterile. It appears that the apparatus of Irwin is a roasting device used in the culinary arts. It would not be obvious for the roasting device of Irwin to be sold as "sterile." First of all, Irwin gives no indication that its device would be for single use only and would have a need to be sold as sterile. The roasting device of Irwin instead appears to be washable and very likely to be used over and over again as would other roasting devices. The type of "cleanliness" that one achieves when he or she washes dishes (which would include roasting devices) is certainly not equivalent to making something surgically sterile. It would be extremely unlikely and certainly not obvious for a roasting device to be "sterilized" with toxic gas, heat, boiling, or gamma radiation. Instead, it would be very likely that the cleaning process for a roasting device to involve common dish soap and warm water, a process which may make something clean but not "sterile." Secondly, as most people who practice the culinary arts know, it would not be at all unusual to find a label somewhere on the packaging of a roasting device that states before use, wash with warm water and a mild soap. This communicates to the user that which they probably already know, the device is neither sterile nor clean at the time of purchase, nor would it be an expectation for a user to "sterilize" the device as it is only recommended that warm water and soap be used to clean it.

Since it would be extremely unlikely for a cook to truly "sterilize" culinary devices, it would not be "obvious" for the apparatus of Irwin to be made "sterile." Therefore the obviousness rejection of Claim 7 is not appropriate.

In addition, Claim 7 depends on Claim 1. As stated above, Claim 1 was amended prior to the mailing of this office action and the new amendment has not yet been considered by the

Page 17 of 21

Amendment Dated: December 7, 2004 Reply to Office Action of December 1, 2004

Examiner. Applicant respectfully requests that the Examiner withdraw this rejection to Claim 7. Review of Claim 7 with respect to currently amended Claim 1 is requested.

#### Claim 8

For convenience, Claim 8 is quoted below.

8. The apparatus of claim 7 further comprising a wrapper surrounding the first and second ends.

Claim 8 depends on dependent Claim 7 which depends on independent Claim 1. As stated above, Claim 1 was amended prior to the mailing of this office action and the new amendment has not yet been considered by the Examiner. Applicant respectfully requests that the Examiner withdraw this rejection to Claim 8. Review of Claim 8 with respect to currently amended Claim 1 is requested.

#### Claim 9

For convenience, Claim 9 is quoted below.

9. The apparatus of claim 1 further characterized as made of plastic.

Claim 9 depends on independent Claim 1. As stated above, Claim 1 was amended prior to the mailing of this office action and the new amendment has not yet been considered by the Examiner. Applicant respectfully requests that the Examiner withdraw this rejection to Claim 9. Review of Claim 9 with respect to currently amended Claim 1 is requested.

Amendment Dated: December 7, 2004

Reply to Office Action of December 1, 2004

### **Allowable Subject Matter**

## Claims 11-15, 17-19, 21-23, and 27-31

The Examiner states that Claims 11-15 and 17-19 are allowable over the prior art of record. The Examiner states that:

the prior art of record fails to teach or render obvious the overall claimed invention of a helical suture instrument and apparatus having a first end and a second end, the first end comprising a spatulate member having a first length along a first axis; the helical suture instrument having a cylindrical axle defining a second axis and a helical portion, the helical portion having a helical outer diameter and having a second axial length along the second axis, the second end of the apparatus comprising a guide shaped to receive the cylindrical axle for rotation on the second axis

As the Examiner did not appear to consider the amended claims discussed above, Applicant assumes that the Examiner also did not consider the Amendments made to Claims 11 and 19 on November 22, 2004. Based on this assumption, Applicant now adds new Claims 21 and 22 which are the same as the text of Claims 11 and 19 prior to the Amendment of November 22, 2004. Applicant also adds Claim 23 which recites the above text which the Examiner states is allowable. Applicant also notes that since the Amendments of November 22, 2004 only narrowed Claims 11 and 19, they still should be allowable. Since for all practical purposes Claims 21, 22, and 23 have already been favorably examined as Claims 11 and 19 and the examiner allows the above text, Claims 21, 22, and 23 should also be allowed.

New Claims 27-31 have been added. They contain the same text as Claims 12-15 and Claim 18 with the exception that they all depend on Claim 21 instead of Claim 11. Since the Examiner already allowed the text of these claims when they were Claims 12-15 and 18 and were dependent on Claim 11 (which is now Claim 21), Claims 27-31 should be allowed.

Amendment Dated: December 7, 2004
Reply to Office Action of December 1, 2004

Applicant notes that Claim 11 of the Amendment submitted on November 22, 2004 contained a typographical error. The line following the claim of "the first and second axes constrained to lie within a single plane each lying within a plane" was inadvertently left behind as the claim was edited for the amendment. Claim 11 is newly amended in this application to remove the line.

#### Claims 2, 3, 5, and 24-26

The Examiner states that "Claims 2, 3, and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims."

Applicant has added new Claims 24-26 which are Claims 2, 3, and 5 rewritten in independent form. Based on the above statement made by the Examiner, Claims 24-36 should be allowable. As for Claims 2, 3, and 5, Applicant submits that they all depend on independent Claim 1. As stated above, Claim 1 was amended prior to the mailing of this office action and the new amendment has not yet been considered by the Examiner. Applicant respectfully requests that the Examiner withdraw this rejection to Claims 2, 3, and 5. Review of Claims 2, 3, and 5 with respect to currently amended Claim 1 is requested.

#### Claim 20

New Claim 20 was added by the November 22, 2004 amendment. Claim 20 does not appear to have been reviewed by the Examiner. Applicant respectfully requests that the Examiner review Claim 20.

Amendment Dated: December 7, 2004 Reply to Office Action of December 1, 2004

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

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